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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Paul P. Latta
App. No. : unknown
Filed : September 12, 2003
For : PREVENTION OF DIABETES THROUGH
INDUCTION OF IMMUNOLOGICAL
TOLERANCE (as amended)
Examiner : Schwadron

DECLARATION OF DAVID SCHARP, M.D.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Dear Sir:

1. I, David Scharp, M.D., am Chief Scientific Officer of Novocell, Inc. At Novocell, I am actively engaged in research related to development of treatment of diabetes using encapsulated insulin-producing cells.

2. Novocell, Inc. is a mid-stage biopharmaceutical company developing a unique encapsulated cell implantation technology for the treatment of diabetes and other serious diseases and disorders. The inventor of the above-captioned application is the president of Novocell. Novocell has an option to license the technology disclosed and claimed in the present application.

3. I have over 30 years of experience working in the area of cell biology. A copy of my C.V. is attached as Exhibit A.

4. Working with the sole inventor of the present application, Paul P. Latta, and others, I carried out experiments to evaluate the efficacy of prevention of diabetes using encapsulated islet cells, as described in the specification of the present application.

5. To evaluate the efficacy of these techniques, I developed a protocol for prevention of diabetes in NOD mice using encapsulated murine islets. The objective was to implant

encapsulated C57B6 islets into diabetes prone NOD mice at different doses, and at different times, prior to the normal onset of spontaneous diabetes, to see if immune destruction of NOD mouse islets could be prevented.

6. For purposes of the experiments described herein a mouse is defined as being diabetic when its blood glucose level was >250 mg/dl on three consecutive occasions. Typically, spontaneous autoimmune diabetes has developed in 80% of NOD mice by 112 – 140 days of age.

7. Islets from mouse strain C57B6 were encapsulated by PEG conformal coating as described in U.S. Patent No. 5,529,914. This patent was incorporated by reference into the specification of the application captioned above at page 13, line 15. The conformally-coated islets were implanted by intraperitoneal injection into NOD mice. C57B6 islets contain an MHC mismatch to the NOD strain. Thus, in the absence of conformal coating, rejection of the islets would be expected.

8. NOD mice were divided into groups with two different variables: (a) time of implant of encapsulated islets (4, 8 or 12 weeks of age) and (b) dose of islets (untreated controls and 50, 100 or 150 encapsulated islets). The mice were followed for 250 days.

9. The results are shown in the attached figures. The figures show bar graphs for the 10 treated mice and 3 untreated mice assigned to each time of implantation group. Mice that remained diabetes-free after 250 days are shown with red bars. One mouse treated with 100 islet equivalents (IEQ) at 12 weeks of age remained diabetes-free until 249 days of age, and is therefore shown with a blue bar.

10. It can be seen that all 9 of the untreated controls developed diabetes prior to 200 days. In contrast, many of the mice treated with encapsulated islets remained diabetes-free after 250 days. In particular, 6 out of the 10 mice treated with encapsulated islets at 4 weeks of age; 5 out of the 10 mice treated with encapsulated islets at 6 weeks of age; and 3 out of the 10 mice treated with encapsulated islets at 8 weeks of age remained diabetes-free. The diabetes-free mice were followed for an additional 50 days, and many of these mice were still diabetes-free at age 300 days.

11. The foregoing results demonstrate that Type I diabetes in a mammal predisposed to develop diabetes can be prevented by implanting insulin-producing cells that are encapsulated in a biologically-compatible membrane, when administered to the mammal prior to clinical onset of Type I diabetes.

12. These series of experiments, and the knowledge of one skilled in the art, demonstrate what is important in developing a method to alter the autoimmunity to prevent ongoing destruction of affected tissues.

13. It is important that the cells are encapsulated, but not the method of encapsulation [macrodevice or microdevice, or macroencapsulation, microencapsulation, microcapsules or conformal coating] or the material used for encapsulation [alginate, PEG, PEG/alginate, agarose, or any of numerous other materials]. It is the physical barrier surrounding the cells that allows the nutrients and oxygen to enter the cell and the antigens from the encapsulated cells to enter the blood, while at the same time the physical barrier prevents the immune system from killing the cells producing the immunological response. Additionally, the encapsulation allows the continuous, chronic release of antigens from the cells to effect the correct response from the immune system to stop the autoimmune destruction.

14. It is important, in relation to the onset of the autoimmune disease, when and how many encapsulated cells are transplanted into the animal, but not where the transplantation site is located in the body. I believe it is the timing of transplantation and amount of cells that stops the autoimmune destruction, and not whether the transplantation site is subcutaneous, intramuscular, intraorgan, arterial/venous vascularity of an organ, cerebro-spinal fluid, or lymphatic fluid, since all allow interaction between the encapsulated cells and the immune system.

15. It is important that the cells, which are encapsulated, release antigens specific to the autoimmune response against which the autoimmune destruction is focused, but not that the cells be a specific type or from a specific organ.

16. It is important that it is an autoimmune disease for which immune protection is sought, but not the specific autoimmune disease since there is a common mechanism by which protection from autoimmune destruction is developed in the body.

17. The method of preventing autoimmune destruction by the chronic exposure of the mammal to antigens, which elicit an autoimmune response, that are continuously released from the encapsulated cells takes advantage of two important regulatory functions in the immune system to determine "self" and "non-self". The invention induces a self tolerance using the body's natural "self-tolerance" mechanism. Autoimmune diseases are caused by a breakdown in the normal self recognition process of the immune system. Correcting this breakdown, well

before serious damage is done to the body alleviates the autoimmune disease and prevents the eventual tissue damage.

18. The critical aspect of the invention is correcting this breakdown after it has begun but prior to irreversible damage has occurred, and thus promoting the re-establishment of self acceptance to the antigen.

19. An autoimmune disease is not, *per se*, a disease in the classical sense caused by bacteria or viri. Autoimmunity is defined as breakdown of mechanisms responsible for self tolerance and induction of an immune response against components of the self. The immune system incorrectly identifies self proteins as foreign and mounts an attack against the body's tissue. Left unchecked, the immune response continues to accelerate until it destroys the tissue releasing the antigen and causes serious metabolic problems or death. Both antibodies and effector T cells can be involved in the damage in autoimmune diseases.

20. The exact etiology of autoimmune diseases is not known. However, various theories have been offered. These include sequestered antigen, escape of auto-reactive clones, loss of suppressor cells, cross reactive antigens including exogenous antigens (pathogens) and altered self antigens (chemical and viral infections). Some of these may also be on a background of gene expression that makes the destruction easier.

21. Although the agent that causes the immune system to make the initial error in the recognition of self and begins the onset of the autoimmune disease may be different for each syndrome, the mechanisms of the immune system in the body are the same. Therefore, a method which reverses the unchecked immune response and re-establishes tolerance to "self", will have an universal effectiveness on autoimmune diseases, no matter what caused the error in the first place.

22. Therefore, Type I diabetes can be considered a "Model disease" for autoimmune diseases in general, since the development of autoimmune diseases have a similar pathway, whether it is Type I diabetes, MS, Lupus or any of the other autoimmune diseases. Therefore, a method developed to reverse the onset of Type I diabetes will have universal application to other autoimmune diseases.

23. Preventing or stopping autoimmune destruction is quite different from non-specific immunosuppression and immunodeficiency. It is an active antigen-dependent process in response to the antigen. Like an immune response, eliminating autoimmune destruction is

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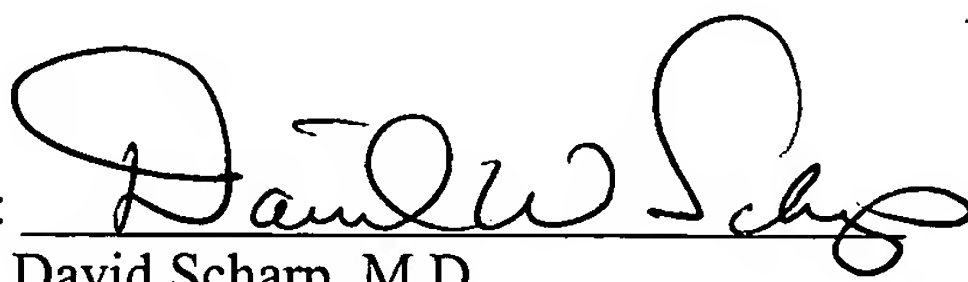
specific and like immunological memory, it can exist in T-cells, B cells or both and like immunological memory, the T cell effect is longer lasting than the B cell effect.

24. The final achievement in preventing autoimmune destruction in humans by the chronic exposure to self-proteins from encapsulated cells may be due to the priming cells being unable to give a second signal to host T cells with the immune effect maintained by the continued presence of the native cells in the recipient.

25. The current invention takes advantage of the body's own immune system to generate "self-tolerance" to an antigen(s) it previously mistook as "foreign", which initiated the autoimmune disease cascade. It is this unique manipulation of the body's own immune system that corrects the previous error of the immune system.

Respectfully submitted,

Dated: 11-25-03

By: 
David Scharp, M.D.
Chief Scientific Officer
Novocell, Inc



CURRICULUM VITAE

David William Scharp, M.D.

Born: July 5, 1945
Washington, Illinois

Social Security Number: 327-36-7524

Marital Status: Wife: Jeanette

Children: Kevin Scharp
Daniel Scharp
Anna Scharp
David Bondurant
Melissa Bondurant

Pre-Medical Education: University of Missouri
Columbia, Missouri
1963-1966

Medical Education: Washington University School of Medicine
St. Louis, Missouri
1966-1970

Graduate Hospital Experience:

Intern in Surgery
7/1/70-6/30/71
Barnes Hospital/Washington University

Surgical Resident
7/1/71-6/30/72 & 7/1/74-6/30/76
Barnes Hospital/Washington University

Surgical Research Fellow
7/1/72-6/30/74
Washington University - Department of Surgery

Academic Positions:

Assistant Professor of Surgery
1976-1983
Washington University School of Medicine

Associate Professor of Surgery
1983-1991
Washington University School of Medicine

Professor of Surgery
1991-President
Washington University School of Medicine

Leave of Absence
1/1/94-7/1/95

Commercial Positions:

Novocell, Inc.
Chief Scientific Officer

Neocrin Company
Chief Scientific Officer 1/1/94-7/31/99
Executive Vice President of Medical Affairs 1/1/94-7/31/99
Executive Vice President for Research 1/1/94-11/1/95
Executive Vice President, Research and Development 11/1/95-President

McDonnell Douglas Corporation 1984-1987
Contractual Research Investigator
Electrophoretic Separation of Islet Cells

Cytotherapeutics, Inc. 1989-1993
Founding Scientist
Scientific Advisory Board Member
Contractual Research Investigator

Patents:

“Islet Isolation Process”

DE191613T – 1987
DE3650662D – 1998
EP0191613 – 1986
EP0191613 – 1989
EP0191613 – 1997
JP61183226 – 1986
US4868121 – 1989
US5322790 – 1994

“Method to Isolate Clusters of Cell Sub-Types from Organs”

AU1934988 – 1989
CA1340406 – 1999
EP0382727 – 1990
EP0382727 – 1991
JP2504222T – 1990
US5079160 – 1992
WO8809667 – 1988

“Implantable Biocompatible Immunoisulatory Vehicle for Delivery of Selected Therapeutic Products”

AT156344T – 1997
AU666118 – 1996
AU682796 – 1997
AU2004192 – 1992
AU3902095 – 1996
CA2109085 – 1992
CA2109085 – 2003
DE69221484D – 1997
DE69221484T – 1998
DK585368T – 1998
EP0585368 – 1994
EP0585368 – 1994
EP0585368 – 1997
ES2107537T – 1997
FI934545 – 1993
FI934545D – 1993
GR3025301T – 1998
HK1001832 – 1998
JP6507412T – 1994
NO308198B – 2000
NO933842 – 1993
SG47470 – 1998

US5798113 – 1998
US5800828 – 1998
US5871767 – 1999
US6083523 – 2000
US6322804 – 2001
US2002150603 – 2002
WO9219195 – 1992

“Methods for Coextruding Immunoisulatory Implantable Vehicles with a Biocompatible Jacket and a Biocompatible Matrix Core”
US5800829 – 1998

“Methods for Treating Diabetes by Delivering Insulin from Biocompatible Cell Containing Devices”

US5869077 – 1999

“Methods for Making Immunoisulatory Implantable Vehicles with a Biocompatible Jacket and a Biocompatible Matrix Core”
US5834001 – 1998
US5874099 – 1999

“Use of Pouch for Implantation of Living Cells”
AU4788993 – 1994
CA2140905 – 1994
EP0655910 – 1995
EP0655910 – 1996
JP8500033T – 1996
US5916554 – 1999
WO9403154 – 1994

Hospital Appointments:

Assistant Surgeon 1976-1983
Associate Surgeon - 1983-Present
Barnes Hospital, St. Louis, Missouri

Attending Surgeon 1982-1985
Consulting Surgeon 1976-1982
Associate Chief of Surgery 12/86-9/90
Veterans Administration Medical Center, St. Louis, Missouri

Consulting Surgeon 1985-7/95
Acting Chief of Surgery 3/86-12/86
St. Louis Regional Hospital, St. Louis, Missouri

Consulting Surgeon 1976-1985
St. Louis Children's Hospital, St. Louis, Missouri

Consulting Surgeon 1976-1985
Chief of Surgery 1981-1982
St. Louis County Hospital, St. Louis, Missouri

Attending Surgeon 1976-1982
St. Louis City Hospital, St. Louis, Missouri

Licensure: Missouri 1970

Certification: American Board of Surgery 1979
Fellow American College of Surgery 1982
Recertification: American Board of Surgery 1989

Medical Societies:

American College of Surgeons
American Diabetes Association
American Federation of Clinical Research
American Pancreatic Association
American Society for Artificial Internal Organs
American Surgical Association
Association for Academic Surgery
Society of University Surgeons
Tissue Culture Association
American Society of Transplant Surgeons
The Cell Transplantation Society
United Network of Organ Sharing - Region 8
International Pancreas & Islet Transplantation Association

Honors and Awards:

St. Louis Surgical Society Award for Research
Recipient 1973 & 1974
NIH Research Career Development Award
Recipient 1977-1982
NIH NAIMMDD Site Visit Teams
Member 1980-1995

NIH Surgery, Anesthesiology, and Trauma Study Section
Member 1985-1989
Reserve Member Status 1989-1995
World Journal of Surgery
Guest Editor - Islet Transplantation Symposium 1984
“Separation of Islet Cells in Microgravity by Continuous-Flow Electrophoresis”, NASA -
McDonnell Douglas Astronautics Corp. - STS-8, Space Shuttle, “Challenger”,
Experiment 1984

Editorial Reviewer:

Diabetes, Surgery, Journal Clinical Investigation
Grant Reviewer
Canadian Diabetes Association
Medical Research Council of Canada
National Surgical Advisor - Digestive Disease Center of Excellence -
The Humana Corporation 1986-1994
Alpha Omega Alpha - Washington University Chapter - Elected
Faculty Member January 1988
Outstanding Profession/Scientific Employee - Federal Employee of the Year Award
Program - St. Louis Federal Executive Board 1990
The Huddinge Hospital Transplant Lectureship - Annual Meeting of the Swedish Society for
Medical Science, Stockholm, Sweden, December 1990
Council Member - Cell Transplantation Society 1992-Present
Council Member - International Pancreas & Islet Transplantation Association 1993-Present
Editorial Board
Cell Transplantation 1992-1993
Transplantation Science

Committee Appointments:

Washington University Animal Studies Committee
Chairman 1991-1994
Washington University Medical Center Alumni Association
Committee Member 1991-1994
International Juvenile Diabetes Research Foundation Medical Science Review Committee
1990-1993
UNOS Pancreas Subcommittee Member 1991-1995
American Society of Transplant Surgeons Program and Publications Committee 1989-1991
Academic Freedom and Tenure Hearing Committee
Member 1985-1991
Washington University Committee on the Humane Care of Laboratory Animal Member
Member 1984-1990

Operating Room Technician Program
 Forest Park Community College
 Advisory Committee 1976-1995
 Chairman 1986-1995
 Mid-America Transplant Association
 Member Professional Advisory Board 1985-1995
 American Cancer Society Institutional Research Grants
 Washington University Committee for Cancer Research
 Member 1979-1989
 Chairman 1982-1989
 "Health Views" - Editorial Advisory Board
 Member 1984-1988
 American Diabetes Association, St. Louis Chapter
 Research Committee 1985-1988
 Department of Surgery Animal Facility
 Director 1980-1984
 Washington University Faculty Senate
 Member 1981-1983
 Executive Committee of the Faculty Council
 Member 1982-1984
 Clinical Sciences Research Building Animal Surgery Suite
 Director 1984-1985
 Department of Engineering Master Degree Thesis Review Committee:
 1979-John Bergen - "Kinetics of Insulin Secretion from Pancreatic Islets of Langerhans
 and Development of Islet Transplantation Chambers"
 1980-Paul Aegerter - "Microencapsulation of Living Cells to Prevent Immunological
 Response"
 1983-Shiow Meei Lin - "Testing of a Mathematical Model for Islet Transplantation
 Chambers"
 1987-Donna Wilkinson - "Coating of Live Cells with Polysaccharide Derivatives"
 1989-Mary Blanchard - "Quantification of Low Concentrations of Polysaccharide
 Derivatives and Their Effect on Cell Viability"
 1990-Ph.D. Thesis Review, Donna Hawk-Reinhard - "Purification of Pancreatic Islets of
 Langerhans Using Cell Electrophoresis"
 St. Louis VAMC Committees
 Comprehensive Planning Committee
 Chairman 1988-1990
 Administrative Executive Board 1988-1990
 Professional Standards Board 1988-1990
 Research Committee 1988-1994
 District Planning Board 1988-1990

Barnes Hospital Committees

Chaplaincy Committee 1992-1994

Emergency Room Committee 1978-1984

Search Committee for ER Director 1978-1984

Patient Education Parent Committee 1979

Surgery Patient Education Subcommittee Chairman 1981-1988

Tissue Culture Association

Publicity Chairman 1980

Invited Presentations, Selected:

The Kroc Foundation

Islet Transplantation Workshop 1974

Islet Transplantation Workshop 1979

Islet Transplantation Workshop 1982

National Institutes of Health

National Conference on Diabetes 1979

National Conference on Diabetes 1983

Juvenile Diabetes Foundation

Conference on Research Tissue 1981

National Meeting, Keynote Speaker 1984

International Scientific Research Conference 1985

German Diabetes Association, Giessen, West Germany

Islet Transplantation Workshop 1980

Islet Transplantation Workshop 1989

American Society of Artificial Organs

Annual Meeting - Keynote Speaker 1983

Session Co-Chairman 1987

International Symposium on Organ Transplantation in Diabetes

The Hague, Netherlands 1983

International Symposium on Kidney and Pancreas Transplantation

Perugia, Italy 1984

International Islet Transplantation Workshop

Canberra, Australia 1984

XII Congress of the International Diabetes Federation

Madrid, Spain 1985

XIII Congress of the International Diabetes Federation

Sydney, Australia 1989

National Disease Research Interchange

Human Tissue Conference 1985

Human Tissue Conference 1986

Human Tissue Conference 1987

Human Tissue Conference 1990

National Disease Research Interchange - Chairman of Task Force on “Biohazard and Contamination in the Use of Human Tissue and Organs”
Philadelphia, PA 1988

American Diabetes Association National Meeting - Session Co-Chairman for “Forms of Therapy” 1986

Visiting Scientist Program - University of Kansas Diabetes Center
Kansas City, Kansas 1986

Immunology of Diabetes Symposium - Member of International Advisory Committee
Edmonton, Canada 1986

International Symposium on Complications of Diabetes
The Hague, Netherlands 1986

Visiting Professorship - Department of Surgery - University of Minnesota
Minneapolis, Minnesota 1986

May 8th Endocrine Days
Victoria, British Columbia 1987

Second Annual Visiting Professorship in Diabetes - University of Wisconsin
Madison, Wisconsin 1987

First International Course on Transplantation
Venice, Italy 1987

Progress in Organ Transplants, Tissue Replacements and Implants
Sponsored by Biomedical Business International, New York 1987

Josiah Brown Memorial Symposium on Pancreas Beta Cell Transplantation
Los Angeles, California 1987

Seventh Workshop of the AIDSPIT Study Group
Igls, Austria 1988

First international Congress on Pancreatic and Islet Transplantation
Stockholm, Sweden 1987

Thirty-Fourth Annual Meeting of ASAIO, Invited Speaker “Modern Treatment of Insulin Dependent Diabetes”
Reno, Nevada 1988

Sixth Gordon Research Conference on Drug Carriers in Biology and Medicine
Plymouth, New Hampshire 1988

XII International Congress of the Transplantation Society
Sydney, Australia 1988

Second International Congress on Pancreatic and Islet Transplantation
Minneapolis, Minnesota 1989

Biology of Tissue Transplantation Symposium
Bethesda, Maryland 1989

Ninth Workshop of the AIDSPIT Study Group
Igls, Austria 1990

Society for Surgery of the Alimentary Tract Postgraduate Course, “Medical Aspects of Transplantation of the Liver, Pancreas and Intestine”
San Antonio, Texas 1990

Moderator for Pancreas Transplantation Scientific Session - American Society of Transplant Surgeons

Chicago 1990

UCLA Symposium on Molecular & Cellular Biology, "Tissue Engineering"

Keystone, Colorado 1990

The Huddinge Hospital Transplant Lectureship Annual Meeting of the Swedish Society for Medical Science

Stockholm, Sweden 1990

Third International Congress on Pancreatic and Islet Transplantation - Moderator and Plenary Speaker

Lyon, France 1991

European Association for the Study of Diabetes - Plenary Speaker

Dublin, Ireland 1991

Visiting Professor - University of Wisconsin

Madison, Wisconsin 1991

Moderator for Clinical Transplantation-Pancreas and Islets - XVIth International Congress of the Transplantation Society

Paris 1992

American Diabetes Association 53rd Annual Meeting - Plenary Speaker

Las Vegas, Nevada 1993

Fourth International Congress of Pancreas and Islet Transplantation - Plenary Speaker

Amsterdam 1993

IVth Joint Meeting of the Lawson Wilkins Pediatric Endocrine Society and the European Society for Pediatric Endocrinology - Symposium Speaker

San Francisco 1993

American Association for Clinical Chemistry

New York 1993

Publications

Abstracts:

1. Ballinger, W.F., Lacy, P.E., Scharp, D.W. Kemp, C.B., Knight, M. - Isografts and allografts of pancreatic islets in rats. Brit. J. Surg. 60:313, 1973
2. Kemp, C.B., Knight, M.J., Scharp, D.W., Lacy, P.E., Ballinger, W.F. - Islets of Langerhans injected into the portal vein of the diabetic rat. South African Journal of Surgery 11:135, 1973
3. Kemp, C.B., Knight, M.J., Scharp, D.W., Lacy, P.E., Ballinger, W.F. - Proceedings: Implantation of pancreatic islets into the portal vein of diabetic rats. Brit. J. Surg. 60:907, 1973
4. Scharp, D.W., Kemp, C.B., Knight, M.J., Murphy, J., Newton, W., Ballinger, W.F., Lacy, P.E. - Long term results of portal vein islet isografts and allografts in the treatment of Streptozotocin induced diabetes. Diabetes 23:359, 1974
5. Scharp, D.W., White, D.J., Ballinger, W.F., Lacy, P.E. - Transplantation of intact islets of Langerhans after tissue culture. In Vitro 9:364, 1974
6. Knight, M.J., Scharp, D.W., Kemp, C.B., Nunnelley, S.B., Ballinger, W.F., Lacy, P.E. - Cryopreservation of pancreatic islets. European Surgical Research 6(1):89, 1974
7. Ballinger, W.F., Murphy, J.J., Scharp, D.W., Hirshberg, G.E., Karl, R.C., Lacy, P.E. - Isolation and preservation of human islets of Langerhans for transplantation in the treatment of diabetes. European Society for Exp. Surg., Tenth Congress 1975
8. Griffith, R.C., Scharp, D.W., Ballinger, W.F., Lacy, P.E. - A morphologic study of intrahepatic portal vein islet isografts. Diabetes 34(2):419, 1975
9. Dodi, G., Scharp, D., Feldman, S., Maresca, B., Ballinger, W., Lacy, P. - Treatment of exocrine pancreatic dysfunction in diabetic rats by islet transplantation. European Surgical Research 9(1):98, 1977
10. Scharp, D.W., Merrell, R.C., Feldman, S., Ruwe, E., Feldmeier, M., Ballinger, W., Lacy, P. - Long term culture of islets of Langerhans utilizing a rotational culture method. In Vitro 13:174, 1977
11. Scharp, D., Krupin, T., Waltman, S., Oestrich, C., Feldman, S., Ballinger, W., Becker, B - Relationship of abnormal insulin release to fluorophotometry in experimental diabetes. Diabetes 27(2):435, 1978

12. Scharp, D.W., Merrell, R.C., Feldmeier, M.M., Downing, R., Ballinger, W.F. - Pseudo-islet formation and culture from canine isolated pancreatic cells. *In Vitro* 15:216, 1979
13. Rajotte, R.V., Scharp, D.W., Downing, R. Molnar, G.D., Ballinger, W.F. - The transplantation of frozen-thawed rat islets transported between centers. *Diabetes* 28:377, 1979
14. Downing, R. Scharp, D.W., Grieder, M., Ballinger, W.F. - Mass isolation of islets of Langerhans from the dog pancreas. *Diabetes* 28:426, 1979
15. Feldman, S.D., Scharp, D.W., Lacy, P.E., Ballinger, W.F. - Fetal pancreas isografts, cultured and uncultured to reverse Streptozotocin induced diabetes mellitus. *The Association for Academic Surgery* 12:116, 1979
16. Grieder, M.H., DeSchryver-Kecskemeti, K. Gingerich, R.L., Scharp, D.W. - In vitro studies using canine pseudo-islets and rat antrum cultures as models. *UCLA Symposium*, December 3, 1979
17. Scharp, D.W., Feldmeier, M.M., Rajotte, R.V., DeSchryver, K., Bell, M. - Human pseudo-islet formation, culture and preservation. *Diabetes* 29(2):18A, 1980
18. Gingerich, R.L., Scharp, D.W., Grieder, M.H., Dye, E.S., Mousel, K.A. - A new in vitro model to study secretion and biochemistry of pancreatic polypeptide (PP). *Diabetes* 29(2):30A, 1980
19. Bergen, J.F., Mason, N.S., Scharp, D.W., Sparks, R.E. - Insulin inhibition of islets in transplantation chambers. Presented at International Society for Artificial Organs Meetings, Paris, July 8-10, 1981
20. Sparks, R.E., Mason, N.S., Finley, T.C., Scharp, D.W. - Development, testing and modeling of an islet transplantation chamber, *ASAIO Meetings*, Chicago, April, 1982
21. Long, J.A., Adair, W.S., Scharp, D.W. - Hybridoma production against pancreatic cells. *Diabetes* 31(2):20A, 1982
22. Scharp, D.W., Hirshberg, G., Long, J.A. - The effect of islet dosage and time on rat portal vein isografts. *Diabetes* 31(2):162A, 1982
23. Scharp, D.W., Lacy, P.E. - The isolation and alteration of islet tissue for transplantation. *The Tissue Culture Association Meeting*, San Diego, June, 1982. *In Vitro Suppl.* 1, 1982
24. Long, J.A., Adair, W.S., Scharp, D.W. - An immunological approach to islet cell purification. *J. Cell Biol.* 95:4061, 1982

25. Sparks, R.E. Mason, N.S., Finley, T.C., Scharp, D.W. - Design of islet transplantation chambers giving a normal glucose tolerance test. ISAO Meetings, Kyoto, Japan, November, 1983
26. Sparks, R.E., Mason, N.E., Finley, T.C., Scharp, D.W. - Islet transplantation chamber models - assumption for insulin generation and glucose diffusion. International Symposium on Organ Transplantation in Diabetes, The Netherlands, September, 1983
27. Sparks, R.E., Mason, N.S., Scharp, D.W. - Some present directions in research on tissue transplantation chambers. International Conference on Artificial Organs, Glasgow, Scotland, September, 1983
28. Sparks, R.E., Mason, N.S., Finley, T.C., Scharp, D.W. - "A distributed source-model for hybrid artificial pancreas", presented by ASAIO, Toronto, Ontario, Canada, April, 1983
29. Scharp, D.W., Feldmeier, M.M., Olack, B.J., Swanson, C.J., O'Shaughnessey, S.F. - Electrophoretic purification of islet cells for transplantation. Diabetes 33(1):179A, 1984
30. Scharp, D.W., Rajotte, R.V., Kneteman, N.M., Lacy P.E. - Zero gravity electrophoresis of islet cells. 10th International Congress of the Transplantation Society Meeting, Minneapolis, August, 1984
31. Scharp, D.W., Lacy, P.E. - Human islet isolation and transplantation. Diabetes 34(1):5A, 1985
32. Kneteman, N.M., Alderson, D., Scharp, D.W. - Canine pancreatic islet allotransplantation: dose adjusted cyclosporine A vs azathioprine - steroid, Diabetes 34(1):62A, 1986
33. Alderson, D., Kneteman, N.M., Scharp, D.W. - The isolation of purified human islets of Langerhans. Diabetes 34(1):81A, 1986
34. Corlett, M.P., Fonseca, P., Scharp, D.W. - Detrimental effect of warm ischemia on islet isolation in rats and dogs with protection by oxygen free radical scavengers. Diabetes 36(1):223A, 1987
35. Scharp, D.W., Lacy, P.E., Finke, E.H., Olack, B.J. - Seven day culture of Ficoll purified human islets. Diabetes 36(1):222A, 1987
36. Corlett, M.P., Scharp, D.W. - Effect of warm ischemia on islet isolation in rats and dogs. The Association for Academic Surgery, Orlando, Florida, November 1-4, 1987
37. Misler, S., Gee, W., Scharp, D., Manchester, J., Falke, L. - Metabolically regulated potassium channels in human islet cells. Diabetes 37(1):6A, 1988

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Letters, Reviews and Chapters:

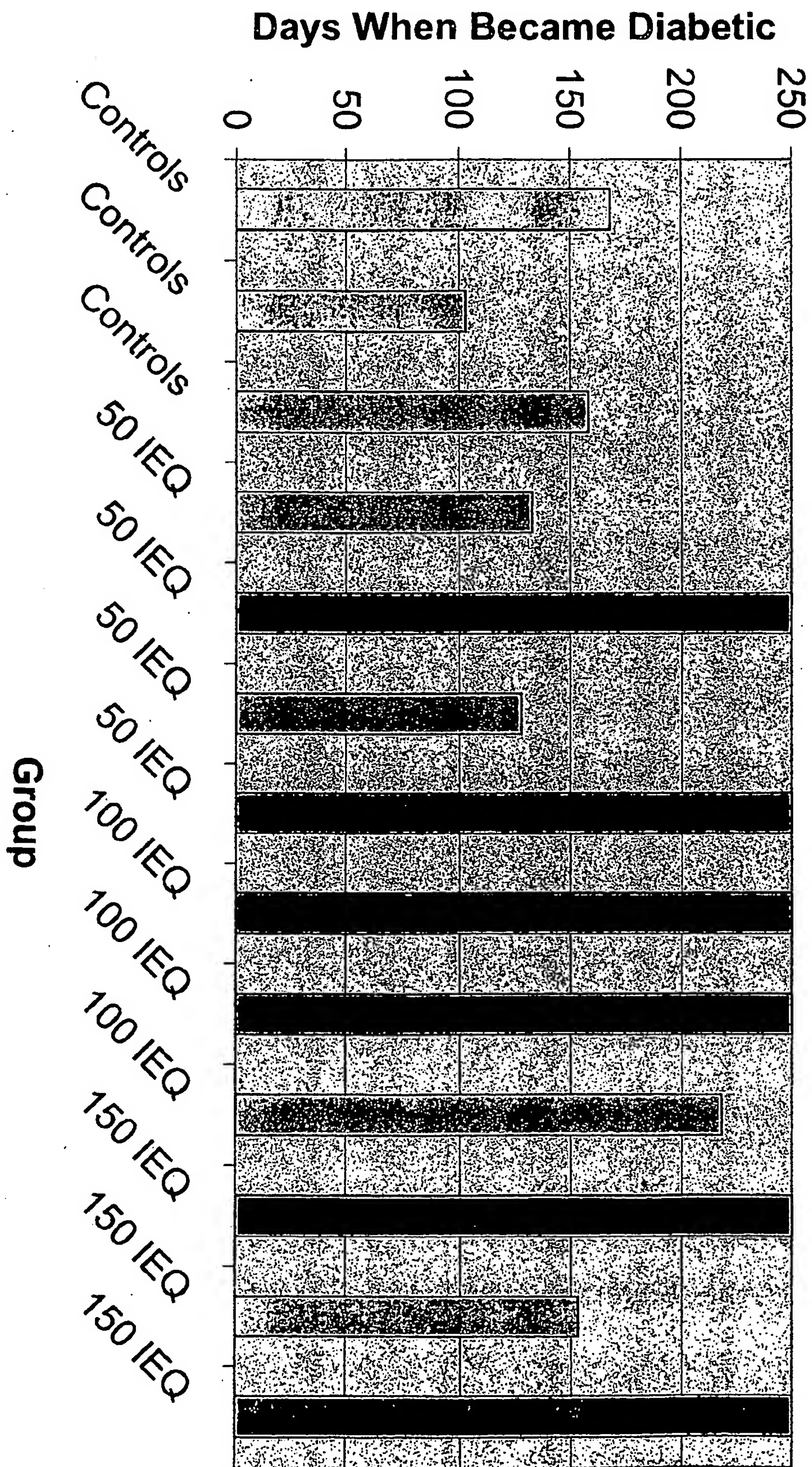
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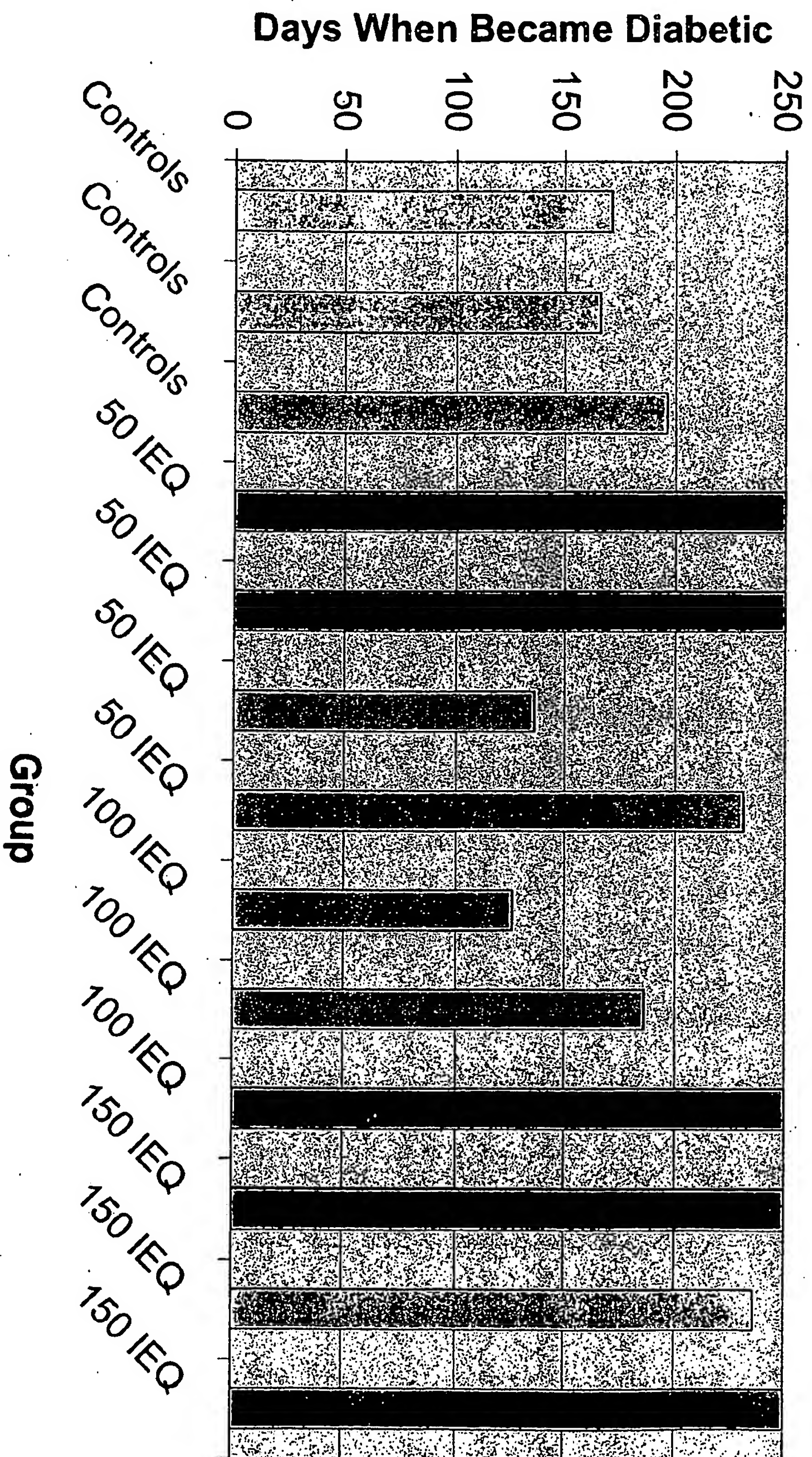
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4 Week Group Age at Diabetes (Red Bars are Recipients Prevented from Developing Diabetes)



8 Week Group Age at Diabetes (Red Bars are Recipients Prevented from Developing Diabetes)



12 Week Group Age at Diabetes (Red Bars are Recipients Prevented from Developing Diabetes)

